

REMARKS**Regarding Priority**

The Examiner indicates that the effective filing date of the claimed invention is 2-11-2000, the filing date of PCT/KR00/00104, because 1999-4860 filed in Korea on 2-11-1999 did not teach isolating EG cells as claimed.

However, referring to the translation of the priority document, the effective filing date should be determined to be 2-11-1999 for that reasons:

Because the claimed invention is described in the specification and claims of the priority document as found in the translation, the priority should be acknowledged. The claimed invention is supported by Examples 1-2 and claims of the priority document and furthermore, the priority document meets the requirements of 35 U.S.C. 112.

More specifically, Examples 1 and 2 of the priority describe procedures for (a) isolation of avian primordial germ cells (PGCs), (b) culturing of PGCs, (c) culturing of embryonic germ (EG) cells and (d) establishment of EG cell lines identical to those described in Examples 1 and 2 of the present application, which are claimed in the instantly pending claim 1. All conditions for culturing cells to obtain established avian EG cell lines such as culturing temperature and time, media and

starting material are identical each other in both the priority document and the present application.

It is noteworthy that the procedures described in the priority document for preparing avian embryonic germ cell lines are completely identical to those of the present application, even though the product from the first step (i) of the priority document is described as PGC colonies and that of the present claim 1 is described as EG cell colonies. Such difference in description of intermediates produced in culturing processes does not render the acknowledgement of priority negative, because the difference is not ascribed to changes in the process but to expression preference of authors who describe inventions.

In this regard, the present invention is supported by the disclosures of the priority document and the effective filing date of the claimed invention is therefore 2-11-1999.

Regarding Rejection under 35 U.S.C. 112

The support for stage 14 to 36 in the present claim 1 can be found on page 5, line 30 and original claim 2 of the present application. The support for stage 24 to 30 in the present claim 29 can be found on page 5, line 31 and original claim 3 of the present application.

The support for feeder layer in the present claim 1 can be found on page 10, line 13 and original claim 5 of the present application. The support for GRSC layer in the present claim 29 can be found on page 10, line 13 and original claim 5 of the present application.

The phrase "EG cell line consisting essentially of undifferentiated avian cells expressing EG cell characteristics" is deleted, so that the rejection as to this is made moot.

The term "EG cell characteristics" is deleted, so that the rejection as to this is made moot.

The support for "form an embryoid body" can be found on page 7, lines 31-32 and Example 3. The support for "capable of differentiating into various cell types" can be found on page 7, lines 31-32 and Example 3.

The support for "chimera expressing the EG cell phenotype" can be found on Example 4. The support for "GRSC layer" in claim 5 can be found on page 10, line 13 of the present application.

The support for employing fibroblast in claims 13 and 37 can be found on page 6, lines 34-37 and page 10, lines 16-19 of the present application. In addition, "[M]itotically active feeder layer" in claim 28 can be found on page 6, lines 34-37 and page 10, lines 16-19 of the present application.

Since claims 1-28 have been cancelled, the rejection of claims 1-28 under 35 USC 112 is moot and requires no further prosecution. This is equally true for the rejection of claims 1-28 under 35 USC 102.

Regarding Rejection of Claims 29-39 Under 35 U.S.C. 102

1. Regarding rejection based on Alloli

In contrast to the Examiner's indications, Alloli does not disclose the preparation of avian EG cell line but only the culturing of PGCs.

The Examiner asserts that the PGCs of Alloli were isolated from the germinal ridge of an avian blastoderm and were pluripotent. However, the PGCs of Alloli were isolated from gonad of 5-day-old embryo as described on page 31, col.2, "Collection of PGCs". In addition, the germinal ridge is not present in avian blastoderm but in gonad. Furthermore, it is unreasonable that the PGCs of Alloli are determined to be pluripotent because Alloli never disclose the differentiation potential of PGCs cultured.

The Examiner indicates that the media used by Alloli for culturing PGCs contains steel factor, LIF and FGF. However, Alloli virtually does not use such factors. As described on page 34, col.1, "Proliferation in Cell Culture", Alloli uses DMEM/F12 medium containing penicillin/streptomycin and glutamine with or

without FCS. The culture with steel factor, LIF and FGF is presented only as a prophet example.

Furthermore, it is evident that the cells cultured by Alloli are not EG cells but PGCs. Long-term culture and subculture necessary to obtain the EG cell line are not performed by Alloli.

The striking feature of the present invention uses a mitotically active feeder layer in culturing and subculturing EG cells as claimed in claim 29 and described on page 6, lines 34-37 and page 10, lines 16-19. However, Alloli does not disclose, teach or even suggest the use of a mitotically active feeder layer. In addition, the present invention uses IL-11 for as an essential ingredient for the survival and proliferation of EG cells, which is not disclosed, taught or even suggested by Alloli.

Consequently, Alloli does not meet all the limitations of the claims and the rejection under 35 USC 102 should be withdrawn.

2. Regarding rejection based on Chang (1995, Cell Biol Internatl. Vol. 19, No. 2, pg 143-149)

In contrast to the Examiner's indications, Chang does not disclose the preparation of EG cells but only the culturing of PGCs.

The Examiner indicates that the PGCs of Chang are isolated from the genital ridge of day 5 chicken embryo. However, Chang describes that PGCs were separated from the embryonic blood on page 144, col.2, 1st paragraph, line 9.

In addition, the Examiner indicates that PGCs of Chang are isolated from the gonad of an avian blastoderm and are pluripotent. However, the avian blastoderm does not comprise the gonad. Furthermore, since the PGCs of Chang are not examined to have the differentiation potential, it is not acceptable to one skilled in the art that the PGCs of Chang are pluripotent.

The Examiner asserts that the cell culture was maintained for at least 4 days. However, Chang describes that GR stroma cells were seeded in wells of 96-well culture plates and incubated for at least 4 days before culture with 5-day-old PGCs. Therefore, the cells cultured for at least 4 days are not PGCs but GR stroma cells.

The Examiner indicates that PGCs isolated from stage 13-14 are equivalent to PGCs isolated from stage 14 as claimed. However, the present invention uses PGCs isolated from the gonad of embryo at stage 20-36 as recited in claim 1. In fact, little or no PGCs are isolated from the gonad of embryo at stage 13-14.

Furthermore, it is evident that the cells cultured by Chang are not EG cells but PGCs. Long-term culture and subculture necessary to obtain the EG cell

line are not performed by Chang. Importantly, Chang does not characterize to verify that PGCs cultured are EG cells.

The striking feature of the present invention uses a mitotically active feeder layer in culturing and subculturing EG cells as claimed in claim 29 and described on page 6, lines 34-37 and page 10, lines 16-19. However, Chang does not disclose, teach or even suggest the use of a mitotically active feeder layer. In addition, the present invention uses IL-11 for as an essential ingredient for the survival and proliferation of EG cells, which is not disclosed, taught or even suggested by Chang.

Consequently, Chang does not meet all the limitations of the claims under 35 USC 102 and the rejection should be withdrawn.

3. Regarding rejection of claims 29-39 under 35 USC 103 based on Chang (1997, Cell Biol Internatl. Vol. 21, No. 8, pg 495-499)

Chang does not disclose the preparation of EG cells but only the culturing of PGCs, contrary to the Examiner's assertion.

The Examiner's assertion, based on the mere fact that cells are able to provide germline transmission, that the gPGCs of Chang are EG cells is unreasonable. It is well known to one skilled in the art that PGCs injected to recipient are also able to provide germline transmission. Furthermore, it is kindly advised that this article was submitted by the present inventors including TAE SUB PARK and

JAE YONG HAN. The present inventors confirm that the gPGCs of Chang are not EG cells.

Moreover, it is evident that the PGCs of Chang are not EG cells but PGCs, in view of the fact that long-term culture and subculture necessary to obtain the EG cell line are not performed by Chang. Chang cultured PGCs only for 5 days, which is considered to be primary culture, as described on page 496, 1st paragraph in "RESULTS". Notably, Chang does not characterize to demonstrate that PGCs cultured are EG cells.

The striking feature of the present invention uses a mitotically active feeder layer in culturing and subculturing EG cells as claimed in claim 29 and described on page 6, lines 34-37 and page 10, lines 16-19. However, Chang does not disclose, teach or even suggest the use of a mitotically active feeder layer. In addition, the present invention uses IL-11 for as an essential ingredient for the survival and proliferation of EG cells, which is not disclosed, taught or even suggested by Chang.

Consequently, claims 29-30 are not obvious in view of Chang.

4. Regarding rejection based on Petite (USP 6,333,192)

As described previously, the effective filing date of the claimed invention is 2-11-1999, the filing date of Korean Patent Application. Accordingly, the withdrawal of this rejection is respectfully requested.

If not so, this rejection should be withdrawn for the reasons indicated hereunder.

The Examiner understands that PGCs cultured for 5 days by Petite become ES cells. However, it is generally appreciated by one skilled in the art that the 5-day culture is only a primary culture. Unlikely, the present invention provides an established EG cell line owing to long-term culturing.

Furthermore, even though Petite discusses that PGCs cultured could develop an ESC phenotype only depending on anti-SSEA-1 staining and cell appearance results, he could not demonstrate that PGCs cultured are pluripotent and capable of providing a chimeric avian. Accordingly, it would be appreciated by one of skill that PGCs cultured by Petite are not authentic EG cell, inter alia, EG cell line.

Petite employs a preconditioned STO feeder layer as an essential element as recited in claim 1. However, the present invention does not use a preconditioned STO feeder layer but a mitotically active feeder layer. Since the mitotically active feeder layer is generally used for cell culturing, the instantly claimed process using it is evidently rendered to be novel and unobvious. In addition, the present invention uses IL-11 for as an essential ingredient for the survival and proliferation of EG cells, which is not disclosed, taught or even suggested by Petite.

Consequently, the rejection of the claims based upon Petite should be withdrawn.

CONCLUSION

Applicants believe that this is a full and complete response to the Office Action. Claims 1-28 have been cancelled and claim 29 has been amended herein. Claims 30-39 are dependent on claim 29. For the reasons discussed above, applicants now respectfully submit that all of the pending claims are in complete condition for allowance. Accordingly, it is respectfully requested that the Examiner's rejections be withdrawn and that claims 29-39 be allowed in their present form.

Should the Examiner require or consider it advisable that the specification, claims an/or drawings be further amended or corrected in formal respects, in order to place the case in condition for final allowance, then it is respectfully requested that such amendment or correction be carried out by Examiner's Amendment, upon receipt of approval from the undersigned on behalf applicants, and the case be passed to issue.

Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

Respectfully submitted
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By: _____


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CERTIFICATE OF MAILING

I hereby certify that this Amendment is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 8, 2005.

Audrey de Souza (Typed or printed name of person mailing paper or fee)

 (Signature of person mailing paper or fee)